

Exhibit 97



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CC: Jim Miller 369 AP6D-2

RE: Medicare Working Group

Attached is the information that Mike Tootell referenced in our most recent Medicare Working Group meeting and which he asked me to circulate. It addresses the topics of average wholesale prices and competitive bidding.

I will contact you soon to schedule our next meeting which will likely be held in January. If you have any comments or suggestions in the interim, please give me a call.

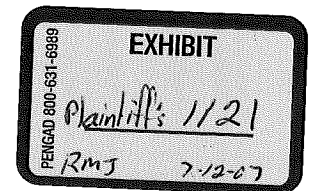
Rich Rieger
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Attachment

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MEDICARE PART B PAYMENT FOR DRUGS
AVERAGE WHOLE SALE PRICE ISSUE

Issue

Currently, Medicare pays for those drugs that are not reimbursed on a prospective payment basis or a cost basis at the lesser of the average wholesale price or the actual acquisition cost of the drug. In actuality, however, Medicare pays at the average wholesale price level, because the program has not acquired acquisition cost information sufficient to establish reimbursement rates.

There have been several studies and investigations into the appropriateness of using AWP as the determining factor for payment. The common conclusion of these efforts is that the use of AWP as a payment measure results in excessive reimbursement that is far out-of-line with the estimated acquisition costs of the drugs, and that AWP has little meaning to the drug manufacturer or the pharmacy to which it sells the drug. In other words, there is some evidence that often the AWP for a drug is set at a particular level to establish third-party reimbursement, but has no relevance to any party beyond the third-party payer. For these reasons, the AWP issue is being presented and considered not as a program policy issue, but rather as an issue steeped in fraud, abuse, and waste. In that context, policymakers appear to focus less on developing good and better policies and more on reducing costs lost to suspected fraud and abuse.

Industry Options

The industry can, of course, attempt to maintain AWP as the payment measure for Medicare-covered drugs, and resist all efforts within Congress and HCFA to change the current formula and practice. In all likelihood, that is not a sustainable position, especially in light of the fraud and waste connotations the investigators have brought to the issue. In addition, numerous people from within the industry have conceded publicly that AWP makes little sense as a basis for reimbursement. At the very least, it will be difficult to make a strong case for the retention of AWP as the determinant of Medicare payment for drugs.

The question arises, then, as to whether the industry can unite around a different approach. For the purposes of this paper, the "industry" consists of the wide range of entities that have interests in pharmacy, but excluding pharmaceutical manufacturers.

Perhaps a unified position can develop around the recognition that AWP is an imperfect surrogate for the array of activities that pharmacists must undertake to provide patient-specific pharmaceutical services. While AWP may be in excess of the acquisition cost of a drug (plus a reasonable markup), it does enable pharmacists to be reimbursed, albeit indirectly, for the necessary pharmaceutical services they do in fact provide. Since Medicare does not acknowledge the existence of these services, and thus does not provide for separate or additional reimbursement for them, the current use of AWP is the only means of paying pharmacists for what they actually do for Medicare beneficiaries.

In light of the foregoing, it may be possible for the industry to endorse the following proposal:

Join with the OIG et al on the proposition that AWP as a payment measure should be replaced with a new mechanism that more accurately reflects the pharmacists' costs. Importantly from our perspective, the new mechanism also must encompass the professional services that pharmacists provide to Medicare beneficiaries. It would be reckless for the government to impose a reduction in payment below AWP without contemporaneously identifying the professional services that HCFA wishes for pharmacists to provide to Medicare beneficiaries. These services warrant reimbursement separate from the drug itself.

Thus, payment for a drug could be reduced, perhaps significantly in some cases, because Medicare's drug reimbursement would reflect only the drug and not related services. If the services are treated separately, subject to effective documentation requirements to give the program adequate assurances that the services are (1) medically necessary and (2) actually being provided, then Medicare would be able to purchase such services where necessary on its beneficiaries' behalf. If reimbursement, then, is calculated to reflect the actual costs of all that pharmacists must do to provide medically necessary care, then it will be fairer and more accurate than AWP.

R.Medicare.PartB1.

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COMPETITIVE BIDDING AND YOU, THE CONSUMER

April, 1996

WHAT IS COMPETITIVE BIDDING?

Competitive bidding is intended to reduce costs to the Medicare program. In most instances, the lowest bidder in each region is awarded the right to provide services to all Medicare beneficiaries. The words competitive bidding are deceiving. The proper terminology should be "Cheapest Health Care Program Available." Previous competitive bidding programs have jeopardized the health of patients. Competitive bidding destroys competition and undermines patient care.

Competitive bidding is not synonymous with competition. In fact, competitive bidding destroys competition by allowing a winner-take-all situation and driving other providers out of business, particularly small providers. Ultimately, this will drive up prices. True competition compares service and price. Competitive bidding looks only for the lowest price. It does not address issues of service, choice or quality. Our coalition strongly believes in competition, as do most of you, but competitive bidding is not true competition. Competition is occurring on a daily basis in the open market.

Both the Administration and Congress endorse the expansion of managed care in the health care market. Like managed care, the desire to implement competitive bidding is based on achieving the lowest cost. However, any structure that permits low bidders to offer inferior quality at below market prices will leave Medicare beneficiaries worse off and will cost more in the long run. We know of no competitive bidding program to date has successfully ensured the level and quality of support and service essential to basic patient care.

WHY IS THE GOVERNMENT TRYING TO IMPLEMENT COMPETITIVE BIDDING?

Concern over the rising federal deficit has prompted both the Administration and Congress to seriously consider the implementation of competitive bidding for clinical laboratory services, durable medical equipment (DME), and parenteral and enteral nutrition (PEN) under Medicare. Eventually, other areas may be affected, such as orthotics and prosthetics (O&P) or orthopedic braces and artificial limbs.

HOW WILL COMPETITIVE BIDDING AFFECT ME?

Competitive bidding compromises quality, access and choice. Exclusive winner-take-all contracts will create government-sanctioned monopolies. If the provider awarded the contract fails to meet quality or volume expectations, alternate contractors might not exist.

Previous competitive bidding projects that have failed give us the ability to predict what would happen if competitive bidding was implemented on a larger scale:

- A young woman recently died as a result of cervical cancer that was misread in three pap smears and three biopsies. Last year, this young woman testified before a House Judiciary Subcommittee that the HMO's competitive bidding process "encouraged the lab owner to provide its services at artificially low prices, and led to the severe lack of quality control and excessive work loads."
- Competitive bidding for certain selected home medical equipment (HME) items has been tried or considered and subsequently abandoned in a number of states. States found competitive bidding to impair freedom of choice for recipients, to render the states incapable of utilizing the expertise of all vendors, and to impede competition and access. Ohio Medicaid officials concluded that competitive bidding was unworkable after issuing a request for purchase. Montana abandoned competitive bidding, because the program was found to deny access to beneficiaries and impair the ability of the state to tap the expertise of all providers. South Dakota backed away from a decision to implement competitive bidding after deciding it could reduce Medicaid costs in other, more effective, ways.
- When the Air Force used competitive bidding for pap smears, the lowest bidding laboratory performed so inadequately that the Air Force had to impound more than 700,000 specimens for retesting.
- Competitive bidding also has worked poorly for both the Defense Department and the Veterans Administration (VA), where it has been employed on a large scale similar to what Medicare may require.

Consumers must not lose access to high quality care for health services such as:

- Parenteral and enteral nutrition (PEN). PEN therapy allows consumers with limited or no function of their gastrointestinal tracts to receive life-sustaining liquid nutrients through a catheter or feeding tube. Specially trained nurses and pharmacists, working in conjunction with the consumer's physician, are required to administer these therapies safely and effectively. Competitive bidding would require providers to submit bids based only on the cost of offering nutrients and supplies, not services. This will deny patients access to quality care and drive quality PEN providers out of the Medicare business.
- Durable Medical Equipment (DME). Medicare beneficiaries do not seek durable medical equipment such as oxygen therapy as a matter of discretion. To receive home oxygen, patients must meet a strict arterial blood gas test, pay a 20% co-payment, and have a physician prescription. When service is interrupted, consumers must receive prompt service or be forced to enter the hospital. Quality home medical equipment service companies maintain 24-hour, seven day a week support so that service is never interrupted. That level of service would be difficult to maintain in a competitive bidding environment. Consumers with emergencies end up entering the hospital at additional Medicare program costs.

- Clinical Laboratory Services. The nations independent clinical laboratories play a crucial role in health care through the early detection, diagnosis, and prevention of disease. Competitive bidding for these services would impede both quality and access to laboratory testing. There are strong incentives to submit "low ball" bids to win a contract, which could ultimately prevent the laboratory from having the resources necessary to assure high quality testing. Many laboratories now offer daily courier pick-ups, 24-hour turn around time for test results, and many other services. Providing these types of customized services is especially costly in rural areas. These severe cost constraints imposed on the winning bidders will likely decrease the quality of services and even make them unavailable in some areas. This potential to put laboratories out of business, leaving a limited selection of laboratories to control the market, is the antithesis of "competition."
- Orthotics and Prosthetics. Competitive bidding can have a dramatic negative impact on the quality of highly customized devices such as orthoses and prostheses (orthopedic braces and artificial limbs), which are designed, fit, and fabricated to the unique needs of the patient. Competitive bidding does not take into consideration the multitude of technological advancements that have been made available in these devices and will inevitably lead to the provision of poor quality and low technology health care as O&P providers attempt to meet the lowest bid.
- Home Care Services. It was the development of vigorous competition that enabled the home health agency infrastructure to respond to the challenge of the 1982 implementation of the Medicare Diagnostic Related Group system for hospitals. This reimbursement change led to the earlier discharge of patients from hospitals to the home, and in a much poorer state of health. Home health agencies responded by developing technological and service innovations, continuous quality improvement programs, and systems to demonstrate quality, outcomes, and consumer satisfaction. This competition has led home health agencies to the point that they are able to provide every services short of surgery in the patient's home. Should competitive bidding narrow provision of home health services to a handful of agencies with a guaranteed steady stream of patients, the small business infrastructure responsible for this progress will be destabilized. The positive competition which has so benefited the consumer will give way to a competitive process focused much more narrowly on price. Consumers will be the primary loser when upon receiving inferior care they find that they have lost the ability to transfer to a provider offering greater access and services of excellent quality.

Please call the President and your Members of Congress today and let them know that You, as a consumer of health care, believe that competitive bidding for any health care services is bad policy.

Phone Numbers

Congress can be reached by calling the Capitol switchboard (202) 224-3121. Ask for the office of the Member of Congress with whom you would like to speak: ask for the legislative assistant who handles health care.

The President can be reached by contacting the White House at (202) 456-1414 or the White House Comment line at (202) 456-1111.

The Coalition to Preserve Health Care Quality and Competition
(NAMES)

National Association of Medical Equipment Services
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GLOSSARY

Clinical Laboratory Services Clinical laboratory testing plays a critical role in the detection, diagnosis and treatment of disease. Appropriate testing enables a physician to make an early diagnosis and implement the correct treatment, which saves lives and reduces overall health care costs. Independent laboratories play an integral role in providing quality testing services. In 1992, approximately 35% of laboratory testing was conducted by independent laboratories, 48% by hospital laboratories, and 17% by laboratories located in physician offices. Together, these clinical laboratories offer more than 2,400 types of tests, provide the most advanced testing available anywhere in the world, and play a vital role in our nation's health care delivery system.

Consultant Pharmacy Services Consultant pharmacists provide medication distribution and consultant services to manage and improve drug therapy outcomes of individuals residing in long-term care environments. Pharmacists serve the full spectrum for the mentally retarded, correctional institutions, hospices and home care. Along with consultant pharmacy services to ensure accurate dispensing, administration and drug therapy review management, pharmacists also provide quality care for patients suffering from wounds of the skin, oxygen therapy for patients suffering from respiratory ailments, and nutritional assistance therapy for patients with gastrointestinal disorders. The patient base consists primarily of the elderly, the chronically and terminally ill, and the mentally retarded. It is estimated that consultant pharmacists provide these essential health care services to at least 2.5 million patients annually.

Durable Medical Equipment Services Home medical equipment (HME) services, sometimes called durable medical equipment (DMB), plays a critical role in home health care by allowing patients to be discharged from institutions soon and recover from their illnesses or injuries at home where they prefer to be. HME providers are usually small, local independent businesses who would be severely impacted by the implementation by Congress of competitive bidding legislation for HME. In fact, of NAMES member companies, in 1994, 82% had revenues under \$2.5 million/year, and 96% had revenues under \$5 million/year. Quality HME providers maintain 24-hour, seven day a week patient support, especially for oxygen therapy patients. That level of service would be improbable to maintain in a competitive bidding environment for HME. As a result, elderly patients with respiratory emergencies would end up at a hospital emergency room at an additional cost for the Medicare program.

Parenteral and Enteral Nutrition (PEN) PEN therapy is indicated for patients who cannot ingest enough nutrients orally to maintain weight and strength. Parenteral nutrition involves administration of sterile, specially mixed solutions through a surgically implanted catheter into a large vein above the heart. Enteral Nutrition is administered directly into the gastrointestinal tract via a tube placed in the stomach or intestine. PEN providers employ nurses, pharmacists, dietitians and other professionals to care for patients in their homes. Without these clinical services, PEN therapy would be impossible to provide safely in the home.

Orthotics and Prosthetics The fields of orthotics and prosthetics (O&P) are engaged in the design, fitting, and fabrication of custom orthopedic braces and artificial limbs to suit the unique medical and functional needs of a wide variety of persons with physical disabilities.

Approximately 3200 ABC-certified orthotists and prosthetists in 1200 ABC-accredited facilities throughout the country enable the hundreds of thousands of amputees and millions with orthopedic impairments to maximize their function and independence.

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R.Medicare.PartB2.

Competitive Bidding for Laboratory Services

Questions and Answers

1. How are Clinical Laboratory Services currently paid for by Medicare?

Medicare Part B currently reimburses clinical laboratories based on the *lower of* actual charges, the fee schedule or the national limitation for a particular test.

Since July 1, 1984, the predominant means by which clinical laboratory services under Part B of Medicare have been reimbursed is on the basis of a fee schedule, which established the reimbursement amounts at 60 percent of the prevailing charges to patients and third party payors. Congress eliminated coinsurance for clinical laboratory services due to the reduction in reimbursements and required that all providers performing clinical laboratory services bill Medicare carriers directly. There was to be no patient billing. The fee schedule was to be updated annually by a cost-of-living adjustment. Prior to that time, clinical laboratory services were based on reasonable cost for testing performed by hospitals for outpatients and reasonable charge for all other providers.

To reduce carrier or regional disparities in reimbursement amounts, on July 1, 1986, Congress first imposed a national limitation amount of 115 percent of the median of all fee schedules. The national limitation has steadily declined to 76 percent of the national median on January 1, 1995. Moreover, there was to be no update in the cost-of-living for 1994 and 1995. The current national limitation amount is 76 percent.

2. What is the Health Care Financing Administration (HCFA) proposing to do?

HCFA is proposing to implement a demonstration project to attempt to rely on competitive bidding to establish the price of clinical laboratory services under Medicare Part B. The project would limit participation to only independent clinical laboratories in a geographical area that have sufficient testing capacity to service the geographical area. Smaller independent clinical laboratories that lack capacity would be unable to compete with the larger clinical laboratories and would be excluded from participation in the Medicare program. The average clinical laboratory receives 25 percent of its revenues from Medicare reimbursement.

Moreover, physician office laboratories and hospital laboratories performing testing for outpatients or nonpatients would not be subject to competitive bidding. Those entities would continue to receive the fee schedule amounts for the geographical areas where they are located. They represent approximately 75 percent of all testing performed for beneficiaries and reimbursed under the Medicare program.

Previous competitive bidding models developed for HCFA by ABT Associates, based in Cambridge, Massachusetts, have proposed either a winner-take-all or multiple bid winner

approach. HCFA has not indicated the approach that would be taken under this demonstration project. Congress has previously prevented HCFA from implementing either approach due to concerns that the methodology for the demonstration project was fundamentally flawed.

HCFA would limit bidding to the sixty or seventy more frequently performed tests, rather than expand bidding to encompass the entire menu of tests offered by a clinical laboratory. Of those frequently performed tests, the data used by Medicare to identify those tests is no longer as relevant due to changes in Medicare reimbursement policy for automated chemistry tests that will dramatically reduce utilization and total reimbursement paid for those tests. In addition, HCFA has refused to exercise its regulatory authority to increase reimbursement for testing based on the increased cost to perform testing based on technological changes or the addition of newer more expensive tests. This proposal represents an attempt by Medicare to "cherry pick" rather than examine reimbursement provided for the full spectrum of testing provided by clinical laboratories.

HCFA has not provided a date certain for implementation of the demonstration project. The proposal is currently under development, but it is expected that HCFA would attempt to implement the demonstration project by late 1996 or early 1997.

3. Has competitive bidding every been tried?

Competitive bidding for clinical laboratory services has been tried on a Federal level and in the private sector. On the Federal level, the Department of Defense has utilized competitive bidding for urine drug screens and pap smears. In each instance, severe quality assurance problems arose, even though, in the case of pap smears, quality assurance provisions were written into the contract. The quality assurance problems encountered by the Air Force required a retesting of all pap smears due to the high error ratios that were discovered.¹ Competitive bidding has never been used to procure health care services for Medicare beneficiaries.

Among private payors, health maintenance organizations and other managed care entities have utilized competitive bidding to procure clinical laboratory services. There are many differences between Medicare and these managed care entities, though. First, the managed care entities typically do not control 25 percent or more of a particular market. Second, clinical laboratories structure bids based on a per member per month for all testing services rather than on the more limited test menu being proposed by HCFA. Third, many entities winning bids are part of health systems that bid based on providing an expanded range of health care to patients rather than just clinical laboratory services. Fourth, Medicare beneficiaries typically are older and require more testing than patients enrolled in either Medicare or non-Medicare managed care programs. There are serious doubts whether the managed care experiences with competitive bidding can be translated

¹ "Extramural Report: Competitive Bidding for Health Care Services", Health Care Financing Administration, Department of Health and Human Services, August 1986, p. 38.

to be applicable to an expansion of competitive bidding for clinical laboratory services for beneficiaries previously covered under fee for service.

4. Won't competitive bidding ensure that the Federal government gets the best price by introducing competition into the market?

The clinical laboratory industry is highly competitive. While in the national market, there are only a handful of larger clinical laboratories, in smaller regional markets there are a multitude of providers. Testing is provided not only by independent clinical laboratories, but by physician office laboratories, group practices and hospital systems settings.

Market factors are already at work in the industry as many independent clinical laboratories have been acquired by larger national clinical laboratories. In the hospital market, hospitals providing outpatient or nonpatient testing have been acquired as part of larger hospital networks or hospital systems in order to compete in the health care marketplace.

In the managed care arena, these clinical laboratories are competing to offer the right combination of price, services and quality to win these contracts. Unlike the Medicare proposals on competitive bidding, the clinical laboratories are bidding based on a fixed number of covered lives. Moreover, enrollees are typically younger and healthier than the average Medicare beneficiary. In addition, if they are part of larger health systems, the entities winning the bids can control their costs by providing a continuum of care. In contrast, clinical laboratories winning the bids under Medicare may have no control over the decision to order testing and thus are unable to control their costs by providing other forms of more efficient patient care.

In fee for service medicine, clinical laboratories are working directly with physicians or group practices to secure patient testing. In effect, the physician stands in the position of a wholesale customer to the clinical laboratory. In addition to their private sector patients, these physicians also see Medicare beneficiaries. In attempting to secure a contract for services from a physician or group practice, a clinical laboratory is factoring in the potential of securing all business from a physician.

However, Medicare is not a test orderer but merely a payor for clinical laboratory services under the Medicare fee for service program. In effect, Medicare stands in the position of a retail customer of the clinical laboratory. Since there is no assurance of testing volume for Medicare beneficiaries, there is little incentive to provide discounts for patients covered by Medicare.

Without having the particulars of the competitive bidding model or methodology available, it is difficult to determine if Medicare will receive the lowest price. There are many factors that influence competitive bidding behavior and until the methodology is known, there is no way to predict what influence factors, such as volume, geographical bidding area and capacity of the laboratory will have on bidding. The long-term implications of

the previous proposed models would suggest that the models proposed by HCFA would be anticompetitive and increase prices in the long run by forcing current providers out of the marketplace and lessening competition in the geographical areas targeted for the demonstration.

R.Medicare.PartB3.